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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,823	11/07/2005	Robert K. Yang	1199-13 PCT/US	2398

7590 10/13/2010

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,823	YANG ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *21-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/11/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment, Applicant's Arguments/Remarks and the Information Disclosure Statement (IDS), all filed 08/11/10.

Applicant's arguments filed 08/11/10 with respect to the 35 U.S.C. §103(a) rejections of claims 1-10, 16, 17 and 19-20 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1-28 are pending in this action. Claims 1 and 11 have been amended. Upon further review and consideration, previously withdrawn claims 11-15 and 18 have now been rejoined and examined with the elected invention (claims 1-10, 16, 17 and 19-20). Claims 21-28 remain withdrawn (based on nonelected invention). Claims 1-20 have been examined in this action. Claims 1-20 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 August 2010 has been entered.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11 August 2010 was filed after the mailing date of the Final Office Action on 05/11/10. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell (U.S. Pat. No. 3,444,858).

Russell ('858) discloses a vehicle for administering drugs comprising a sectionalized strip of resiliently flexible gelatinous material of a section which enables a length thereof to be inserted in the buccal cavity, the vehicle containing a drug which is effective when absorbed through the buccal mucous membrane, whereby the strip being so formed or marked at intervals therealong to facilitate it being divided up to provide individual lengths of desired drug content or dosage (see column 1, lines 14-66). The strip is formed with pairs of transverse depressions in opposite major faces so as to divide the strip into a plurality of sections which are each connected to the next adjacent sections by comparatively weak ligaments. The purpose of the

ligaments is to enable the strip to be torn or otherwise divided up into individual lengths each of which consists of one or desired number of sections (col. 2, lines 24-38). These "weak ligaments" read on the "perforations" and "scored weakened sections" instantly claimed. The vehicle contains a predetermined amount of drug (col. 2, lines 60-67). The strip can equally well be divided or graduated into sections, preferably of equal sizes, by single depressions at intervals along the strip, such depressions extending from edge to edge or from side to side of the strip, whereby the strip may be torn across or extending only part of the way across the strip by way of graduations defining the individual sections and providing appropriate indicates for cutting the strip (col. 3, lines 21-39). Russell states that the factors governing the rate of dissolution of the strip and rate of absorption may be controlled by adjusting the composition of the melt (col. 3, lines 65-75). Russell also states that the rate of absorption is remarkably constant (col. 4, lines 70-75). The presence of voids would be inherently present in the strip of Russell that would consequently affect surface area characteristics.

The instant claims are anticipated by Russell.

* * * * *

Claims 1-5, 7-9 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuchs *et al.* (U.S. Pat. No. 4,136,145).

Fuchs ('145) discloses improved medicament carriers in the form of a film having a pharmaceutically active compound uniformly incorporated therein (col. 1, lines 50-65; col. 2, lines 65-67 and Abstract). The medicament is dissolved or uniformly suspended in a film-forming composition to form a homogeneous solution or dispersion which is then drawn with a film-drawing machine into a sheet, dried and then cut into any desired number and size of unit

dosage forms (col. 2, lines 5-19). Upon drawing the wet sheet a film is obtained which is suitable divided such as by simple perforation, which can provide for unit dosages containing different medicaments or different concentrations thereof (col. 4, lines 27-47; col. 3, lines 37-46). This disclosure reads on a film that is perforated or scored. The film has the advantage that medicament is homogeneously and uniformly distributed throughout the medicament carrier (col. 4, lines 17-26). Regarding voids, the presence of voids would be inherently present in the film of Fuchs that would consequently affect surface area characteristics. With respect to the film being "self-supporting", the film of Fuchs is a "self-supporting" film, in the absence of evidence to the contrary. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The instant claims are anticipated by Fuchs.

* * * * *

Claims 1-5 and 7-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitra (U.S. Pat. No. 4,451,260).

Mitra ('260) discloses a flexible, sustained release medicament device for oral administration in the form of a multi-layered film (column 1, lines 46-60) that provides a predetermined selective dose of medicament (col. 2, lines 52-56), wherein the device contains perforations that may be provided at regular intervals to provide for unit dosages (col. 3, line 56 – col. 4, line 10). This disclosure reads on a film that is perforated or scored. The medicament is

homogeneously dispersed in the matrix or it may be desirable to increase the concentration of the medicament from the outer wall to the interior of the carrier film to approach a zero order release behavior (col. 4, lines 59-64). Mitra states that if the medicament is homogeneously dispersed in a single carrier film, the barrier film will overlay both surfaces of the carrier film unless it is desired to have more rapid release of medicament from one surface of the device than from the other (col. 5, lines 48-54). The purpose of the barrier film is to control the rate of release of medicament that is present in the carrier film. The barrier film also provides for buoyancy in that it entraps air in small pockets, or bubbles of air between it and the carrier film (col. 5, line 54 - col. 6, line 36). Thus, this teaching reads on the presence of voids, which would also be inherently present in the film of Mitra and would consequently affect surface area characteristics. With respect to the film being "self-supporting", the film of Mitra is a "self-supporting" film, in the absence of evidence to the contrary. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The instant claims are anticipated by Mitra.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs *et al.* (U.S. Pat. No. 4,136,145).

Fuchs ('145), as discussed above, teaches improved medicament carriers in the form of a film having a pharmaceutically active compound uniformly incorporated therein (col. 1, lines 50-65; col. 2, lines 65-67 and Abstract). The medicament is dissolved or uniformly suspended in a film-forming composition to form a homogeneous solution or dispersion which is then drawn with a film-drawing machine into a sheet, dried and then cut into any desired number and size of unit dosage forms (col. 2, lines 5-19). Upon drawing the wet sheet a film is obtained which is suitable divided such as by simple perforation, which can provide for unit dosages containing different medicaments or different concentrations thereof (col. 4, lines 27-47; col. 3, lines 37-46). This disclosure reads on a film that is perforated or scored. The film has the advantage that medicament is homogeneously and uniformly distributed throughout the medicament carrier

(col. 4, lines 17-26). Regarding voids, the presence of voids would be inherently present in the film of Fuchs that would consequently affect surface area characteristics.

While Fuchs does not teach that the "active varies no more than 10% among said dosage units", (as in instant claim 6), the reference nonetheless, teaches that by merely varying the concentration of the active medicament in the carrier, the thickness of the film and the area of the film employed per unit dosage, the amount of medicament per unit dosage can be varied in an elegantly simple fashion (col. 4, lines 17-26). Thus, the reference recognizes the ability to manipulate the concentrations and therefore, obtain a pre-determined amount of active agent that can be employed in each of the dosage units. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable amounts or ranges of active ingredient by routine experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art.

Thus, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Fuchs.

* * * * *

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitra (U.S. Pat. No. 4,451,260).

Mitra ('260), as discussed above, teaches a flexible, sustained release medicament device for oral administration in the form of a multi-layered film (column 1, lines 46-60) that provides a predetermined selective dose of medicament (col. 2, lines 52-56), wherein the device contains perforations that may be provided at regular intervals to provide for unit dosages (col. 3, line 56

– col. 4, line 10). This disclosure reads on a film that is perforated or scored. The medicament is homogeneously dispersed in the matrix or it may be desirable to increase the concentration of the medicament from the outer wall to the interior of the carrier film to approach a zero order release behavior (col. 4, lines 59-64). Mitra states that if the medicament is homogeneously dispersed in a single carrier film, the barrier film will overlay both surfaces of the carrier film unless it is desired to have more rapid release of medicament from one surface of the device than from the other (col. 5, lines 48-54). The purpose of the barrier film is to control the rate of release of medicament that is present in the carrier film. The barrier film also provides for buoyancy in that it entraps air in small pockets, or bubbles of air between it and the carrier film (col. 5, line 54 - col. 6, line 36). Thus, this teaching reads on the presence of voids, which would also be inherently present in the film of Mitra and would consequently affect surface area characteristics. With respect to the film being "self-supporting", the film of Mitra is a "self-supporting" film, in the absence of evidence to the contrary.

While Mitra does not teach that the "active varies no more than 10% among said dosage units", (as in instant claim 6), the reference nonetheless, teaches that the device of the invention can be prepared with a known amount of medicament per linear measurement (col. 3, lines 62-65). Thus, the reference recognizes the ability to manipulate the concentrations and therefore, obtain a pre-determined amount of active agent that can be employed in each of the dosage units. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable amounts or ranges of active ingredient by routine experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art.

Thus, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Mitra.

* * * * *

Pertinent Art:

Prior Art made of record and cited of interest by the Examiner:

Gardner – U.S. Patent No. 4,126,503 (11-21-1978)

D'Angelo – U.S. Patent Nos. 5,614,212 (3-25-1997) & 6,024,975 (2-15-2000)

Response to Arguments

Applicant's arguments with respect to claims 1-10, 16, 17 and 19-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

--No claims are allowed at this time.

Claims 1-20 are rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

October 12, 2010